

APPENDIX H

GUIDELINES AND CRITERIA
FOR
ON-SITE INSPECTION
OF
COMMERCIAL ANALYTICAL CHEMISTRY LABORATORIES

GUIDELINES AND CRITERIA FOR ON-SITE INSPECTION OF
COMMERCIAL ANALYTICAL CHEMISTRY LABORATORIES

H-1. On-Site Laboratory Inspection Procedures. This document outlines the procedures to be used by the USACE inspectors to conduct an on-site inspection and evaluation of a commercial laboratory. On-site laboratory inspections are carried out to monitor a commercial laboratory's ability to meet selected terms and conditions specified in a USACE HTRW contract and to identify laboratory problems that adversely impact performance. The frequency of on-site inspection is dictated by a commercial laboratory's performance. An on-site inspection generally takes eight hours and normally consists of three parts: entrance interview, laboratory tour, and exit interview. Prior to the inspection, the inspectors shall thoroughly review all project- and laboratory-specific documents. The Pre-Inspection Checklist shown in Figure H-1 can be used as a guidance for preparation of on-site inspection.

a. Entrance Interview. The entrance interview will be held with the laboratory management personnel, including laboratory director/managers, QA officer, and project personnel, to discuss the upcoming USACE projects, USACE Chemical Data Quality Management (CDQM) requirements, PE sample results, USACE review comments on laboratory quality management manual (LQMM), and laboratory's previous performance on USACE projects, if applicable. A copy of written comments on the LQMM should be presented to the laboratory during the entrance interview. The Entrance Interview Checklist shown in Figure H-2 can be used as a guidance.

b. Laboratory Tour. A tour of the commercial laboratory will follow to examine the laboratory facilities, instrumentation, operation, maintenance, documentation, safety, waste compliance, etc. The laboratory tour will emphasize on two separate aspects: Quality Assurance Evaluation and Evidentiary Audit. The questionnaire and checklist presented in Appendices E and I should be used during the laboratory tour.

(1) Quality Assurance Evaluation: The inspectors shall inspect a commercial laboratory's facilities to verify the adequacy and maintenance of instrumentation, the continuity of personnel meeting experience or education requirements, and the acceptable performance of analytical and QC procedures. The items to be monitored will include, but not be limited to, the following items:

PRE-INSPECTION CHECKLIST

1. Gather all appropriate laboratory information from files.
 - a. Preliminary questionnaire.
 - b. Laboratory's LQMM.
 - c. PE sample results and evaluation reports.
 - d. Chemical quality assurance reports (CQARs) on past projects.
2. Gather and review project information.
 - a. Project summary based on specifications, scope of work, work plans, chemical data acquisition plan, etc.
 - b. Analytical parameters and number of samples.
 - c. Project data quality objectives (DQOs).
3. Contact laboratory to set up audit date.
 - a. Get directions to laboratory by FAX.
 - b. Suggest tentative on-site inspection date.
 - c. Briefly review inspection procedures.
4. Contact USACE TM/CORs and district chemists.
 - a. Get most current project information.
 - b. Extend an invitation for them to attend the inspection.
5. Contact laboratory to confirm inspection date and make travel arrangements.
6. Review laboratory's LQMM, questionnaire, and any other qualification documents. Generate written comments.
7. Review laboratory's PE sample results.
 - a. Review and confirm all PE sample results.

Figure H-1 Pre-Inspection Checklist

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- b. Gather any missing information.
 - c. Update database with current information.
 - d. Prepare a summary of PE sample status for review at the laboratory.
- 8. Review the CQARs on past USACE projects that laboratory previously worked on.
 - a. Check with QA laboratory(s) for any detail or missing information.
 - b. Extend an invitation for QA laboratory(s) to attend the inspection.
- 9. Prepare a list of problem areas in laboratory.
 - a. Based on PE sample results.
 - b. Based on past performance on USACE projects.
- 10. Gather general information and forms for distribution at the laboratory.
 - a. ER 1110-1-263.
 - b. Copy of laboratory evaluation request(s).
 - c. "On-site Inspection Summary" format.
 - d. Entrance interview checklist.
 - e. Laboratory inspection checklist.
 - f. Exit interview checklist.
 - g. Cooler receipt checklist.
 - h. USACE minimum data reporting requirements.
 - i. Sample CQAR and data comparison table.
 - j. Your business card.

Figure H-1 Pre-Inspection Checklist (continued)

ENTRANCE INTERVIEW CHECKLIST

1. Personnel introductions.
 - a. Give background of inspectors and USACE HTRW MCX.
 - b. Pass out/gather business cards.
 - c. Pass out and have everyone sign "On-site Inspection Summary" format.
2. Validation process.
 - a. Describe USACE laboratory validation process.
 - Step 1: Preliminary review and screening based on qualification submittals.
 - Step 2: Performance evaluation based on PE sample analysis.
 - Step 3: On-site inspection.
 - b. Explain the approval process after on-site inspection.
 - c. Emphasize that laboratory validation is a parameter, matrix, and method-specific approval.
 - d. A project-specific evaluation is needed for each new project.
3. Project information.
 - a. Is laboratory aware of the project?
 - Is CDAP available? Laboratory should get copies of CDAPs for upcoming projects.
 - Are DQOs available?
 - Make available to laboratory a copy of evaluation request(s).
 - b. Describe projects.

Figure H-2 Entrance Interview Checklist

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4. USACE QA Program.

- a. Pass out a copy of ER 1110-1-263.
 - Describe USACE QA program and special features.
 - It is consistent and complies with Federal and State regulations.
- b. Describe field split QA sample program
- c. Describe government QA Laboratory and its role:
 - Examines incoming field samples against CDAP. Pass out copy of "Cooler Receipt Checklist". Notify TM/CORs immediately if errors noted.
 - Analyzes QA samples. QA Laboratory can be used as a resource to answer questions.
 - Reviews project laboratory's data. Pass out a copy of "USACE Minimum Data Reporting Requirements."
 - Generates CQAR. Describe this report. Pass out a copy of sample "Data Comparison Table" and describe the key elements that are focused on.)

5. Review comments on laboratory's LQMM.

- a. Pass out and review comments.
- b. Discuss corrective actions, if needed.

6. Status of PE sample results.

- a. Summarize current status of all PE samples.
- b. Discuss deficiencies and corrective actions, if needed.

7. Laboratory's performance on past USACE projects.

- a. Discuss data quality based on precision, accuracy, representativeness, comparability, completeness, and sensitivity (PARCCS).
- b. Discuss corrective actions, if needed.

Figure H-2 Entrance Interview Checklist (continued)

- (a) Size and appearance of the facility.
- (b) Quantity, age, availability, scheduled maintenance, and performance of instrumentation.
- (c) Availability, appropriateness, and utilization of SOPs.
- (d) Staff qualifications, experience, and personnel training programs.
- (e) Reagents, standards, and sample storage facilities.
- (f) Standard preparation logbooks and traceability.
- (g) Sample analysis, raw data, bench sheets, and analytical logbooks maintenance and review.
- (h) Data package review and data management procedures.

(2) Evidentiary Audit: The inspectors conducts an evidentiary audit to determine if the laboratory's QA/QC policies and SOPs are implemented to warrant required data quality and legal defensibility. The evidentiary audit is comprised of the following three activities:

(a) Procedural Audit: The procedural audit consists of review and examination of actual operating procedures and accompanying documentation for the following laboratory operations: sample receiving, storage, identification, security, tracking (from receipt to completion of analysis), and analytical project file organization and assembly.

(b) Written SOPs Audit: The written SOPs audit consists of review and examination of the written SOPs to determine if they are accurate and complete for the following laboratory operations: sample receiving, storage, identification, security, tracking (from receipt to completion of analysis), and analytical project file organization and assembly.

(c) Analytical Project File Audit: The analytical project file audit consists of review and examination of the analytical project file documentation. The inspectors shall review the files to determine:

- the accuracy of the document inventory,
- the completeness of the file,

the traceability of sample activity,

the identification of activity recorded on the documents, and

the error correction methods.

c. Exit Interview. At the conclusion of the laboratory tour, the inspectors discuss their findings and recommendations for any corrective actions with the laboratory management staff during an exit interview. A commercial laboratory shall prepare a written report regarding the corrective actions implemented or to be implemented with schedule for completion to the Committee for review and approval. The written report must provide detail on corrective actions for all deficiencies discussed during the exit interview and must be sent within ten working days from the on-site inspection. The Exit Interview Checklist shown in Figure H-3 can be used as guidance.

H-2 . Guidance and Criteria for Sample Management, Data Management, Document Control, and Standard Operating Procedure

a. Sample Management. Sample management procedures are defined as procedures specifying the sample receiving, log-in, storage, and disposal. A sample is a physical evidence collected from a facility or from the environment. Controlling evidence is an essential part of the hazardous waste investigation effort. A commercial laboratory shall establish SOPs to maintain the integrity, authenticity, and legal defensibility of samples from initial receiving to proper disposal. To accomplish this, laboratories are required to develop and implement the following sample identification, chain-of-custody, sample receiving, and sample tracking procedures:

(1) Sample Identification: To assure traceability of the samples while in possession of a laboratory, the laboratory shall have a specified method for maintaining identification of samples throughout the laboratory. Each sample and sample preparation container shall be labeled with a USACE field sample ID number or a unique laboratory identifier. If a unique laboratory identifier is used, it shall be cross-referenced to the USACE field sample ID number.

(2) Chain-of-Custody Procedures: The custody of USACE samples must be traceable from the time the samples are collected until they are introduced as evidence in legal proceedings. A commercial laboratory shall have procedures ensuring that USACE sample custody is maintained and documented. A sample is under custody if:

EXIT INTERVIEW CHECKLIST

1. Express gratitude for laboratory's efforts, cooperation and time
2. Present inspection findings
 - a. Strong and weak areas.
 - b. Deficiencies and corrective actions.
 - c. Recommendations for improvements.
3. Complete the "Inspection Summary" sheets
 - a. Ask laboratory director/manager to review and sign summary sheet.
 - b. Pass out a copy of signed summary sheet.
 - b. Request written responses within ten working days.
4. Invite questions and comments
5. Meeting adjourned

Figure H-3 Exit Interview Checklist

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- it is in your possession,
- it is in your view after being in your possession,
- it was in your possession and you locked it up, or
- it is in a designated secure area that is accessible only to authorized personnel.

(3) Sample Receiving Procedures:

(a) A commercial laboratory must designate a sample custodian responsible for receiving all samples. A representative should also be designated to receive samples in the event that the sample custodian is not available. The sample custodian must inspect the condition of the shipping containers, sample bottles, and the custody seals (intact/not intact) upon receipt. The sample custodian shall also check for the presence or absence of the following documents accompanying each sample shipment:

- Airbills or airbill stickers
- Chain-of-Custody forms
- Sample labels
- Sample tags (if required for a project)

(b) The sample custodian must sign and date all forms (e.g., custody records, packing lists, and airbills) accompanying the samples at the time of sample receipt. A commercial laboratory must immediately contact the prime contractor and/or USACE TM/COR to resolve any discrepancies and problems such as absent documents, conflicting information, broken custody seals, and unsatisfactory sample condition (e.g., leaking sample bottle, improper preservation, etc.) A commercial laboratory shall record the resolution of discrepancies and problems on a phone conversation log. All records and logs shall become part of the project file records.

(c) The following information shall be recorded in sample logbook by the sample custodian or his/her representative as samples are received and inspected:

- Condition of the shipping container
- Presence or absence and condition of custody seals on shipping and/or sample containers

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- Custody seal numbers, when present
- Condition of the sample bottles
- Presence or absence of airbills or airbill stickers
- Airbill or airbill sticker numbers, when present
- Presence or absence of packing lists
- Presence or absence of sample tags
- Sample tag identification numbers, when present
- Verification of agreement or non-agreement of information recorded on shipping documents and sample containers
- Problems or discrepancies
- Resolutions for problems or discrepancies

(d) The Cooler Receipt Checklist as shown in Figure H-4 or a similar one is strongly recommended.

(4) Sample Tracking Procedures: A commercial laboratory shall maintain records documenting all phases of sample handling from receipt, analysis, and final sample disposal.

(5) Sample Disposal Procedures: A commercial laboratory shall treat all USACE samples, including residual samples, digested or extracted samples, samples with analyses cancelled, sample containers, waste generated during sample preparation or analysis, etc., as potential hazardous and toxic material or substance until proven otherwise. SOPs for disposal USACE samples shall comply with all Federal and State regulations such that the USACE will not be legally liable for improper sample or waste disposal by the laboratory.

b. Data Management. Data management procedures are defined as procedures specifying the acquisition or entry, update, correction, deletion, storage, and security of computer readable data and files. These procedures should be in written form and contain a clear definition for all databases and files used to generate or submit deliverables. Key areas of concern include: system organization (including personnel and security), documentation operations, and traceability. The system should prevent entry of incorrect or out-of-range data and alert data entry personnel of errors through a multilevel review process.

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LIMS #: _____ Chain-of-Custody No: _____ Date received: _____

Project: _____

USE OTHER SIDE OF THIS FORMAT TO NOTE DETAILS CONCERNING CHECK-IN PROBLEMS.

- A. PRELIMINARY EXAMINATION PHASE: Date cooler was opened: _____
by (print): _____ (sign): _____
1. Did cooler come with a shipping slip (airbill, etc.)? YES NO
If YES, enter carrier name & airbill number here: _____
 2. Here custody seals on outside of cooler? YES NO
How many & where: _____, seal date: _____, seal name: _____
 3. Were custody seals unbroken and intact at the date and time of arrival? YES NO
 4. Did you screen samples for radioactivity using a Geiger Counter YES NO
 5. Were custody papers sealed in a plastic bag & taped inside to the lid? YES NO
 6. Were custody papers filled out properly (ink, signed, etc.)? YES NO
 7. Did you sign custody papers in the appropriate place? YES NO
 8. Was project identifiable from custody papers? YES NO
If YES, enter project name at the top of this form.
 9. If required, was enough ice used? Type of ice: _____ YES NO
 10. Have designated person initial here to acknowledge receipt of cooler: _____ (date): _____
- B. LOG-IN PHASE: Date samples were logged-in: _____
by (print): _____ (sign): _____
11. Describe type of packing in cooler: _____
 12. Were all bottles sealed in separate plastic bags? YES NO
 13. Did all bottles arrive unbroken and were labels in good condition? YES NO
 14. Were all bottle labels complete (ID, date, time, signature, preservative, etc.)? YES NO
 15. Did all bottle labels agree with custody papers? YES NO
 16. Were correct containers used for the tests indicated? YES NO
 17. Were correct preservatives added to samples? YES NO
 18. Was a sufficient amount of sample sent for tests indicated? YES NO
 19. Were bubbles absent in VOA samples? If No, list by sample #: YES NO
 20. Was the USACE Technical Manager called and status discussed? YES NO
If YES, give details on the back of this form.
 21. Who was called? _____ By whom? _____ date: _____

Figure H-4 Cooler Receipt Checklist

The record of changes in the form of corrections and updates to data originally generated, submitted, and/or resubmitted must be documented to allow traceability of updates. Documentation must include the following for each change:

- Justification or rationale for the change.
- Initials of the person making the change or changes. Data changes must be implemented and reviewed by a person or group independent of the source generating the deliverable.
- The laboratory manager must approve changes to originally submitted deliverables.

c. Document Control. The goal of a laboratory document control program is to assure that all documents for a specified project will be accounted for when the project is completed. Accountable documents used by commercial laboratories shall include, but not be limited to, logbooks, chain-of-custody records, sample work sheets, bench sheets, and other documents relating to the sample or sample analyses. The following document control procedures should be established to assure that all laboratory records are assembled, stored, and ready for delivery to USACE when requested by USACE:

(1) Preprinted Laboratory Forms and Logbooks:

(a) All observations and results recorded by a commercial laboratory but not on preprinted laboratory forms shall be entered into permanent laboratory logbooks. The laboratory shall identify the activity recorded on all laboratory documents that are directly related to the preparation and analysis of USACE samples.

(b) Preprinted laboratory forms shall contain the name of the commercial laboratory and be dated (month/day/year) and signed by the person responsible for performing the activity at the time an activity is performed. Logbook entries shall also be dated, signed, and entered in chronological order. Pages in both bound and unbound logbooks shall be sequentially numbered. Instrument run logs shall be maintained so as to enable a reconstruction of the run sequence of individual instruments.

(c) Corrections to raw data and supporting documents shall be made by drawing a single line through the error and entering the correct information. Corrections and additions to raw data and supporting documents shall be dated and initialed. No information shall be obliterated or rendered unreadable. All

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notations shall be recorded in ink. Unused portions of documents shall be crossed out.

(2) Consistency of Documentation: A commercial laboratory should assign a document control officer responsible for the organization and assembly of all project related files. All copies of laboratory documents shall be complete and legible. Before releasing analytical results, the document control officer shall assemble and cross-check the information on sample tags, custody records, laboratory bench sheets, personal and instrument logs, and other relevant deliverables to ensure that data pertaining to each particular sample is consistent throughout the specific USACE project.

(3) Storage of USACE Files: A commercial laboratory shall maintain USACE laboratory documents in a secure location that has a limited access. All documents that are directly related to the preparation and analysis of USACE samples shall be stored and made available to USACE upon request within a contract specified time limit.

d. Specifications for SOPs. In order to obtain reliable results, adherence to prescribed analytical methodology is imperative. In any operation that is performed on a repetitive basis, reproducibility is best accomplished through the use of SOPs. An SOP shall be functional: i.e., clear, comprehensive, up-to-date, and sufficiently detailed to permit duplication of results by qualified analysts. All SOPs must accurately reflect actual procedures used in the laboratory, and copies of the written SOPs shall be available to the appropriate laboratory personnel. In addition, all SOPs must be consistent with appropriate, current Federal and/or State regulations and guidelines and with manufacturer's specific instruction manuals.

(1) SOP Format: An SOP is defined as a written document that provides step-by-step description of a laboratory operation, analysis, or actions. The format of an SOP may vary depending upon the kind of activity for which they are prepared; however, at a minimum, the following sections must be included:

- (a) Title page
- (b) Scope and Application
- (c) Definitions
- (d) Procedures
- (e) QC Criteria

- (f) Corrective Action Procedures, including secondary review of information being generated
- (g) Documentation description and example forms
- (h) Miscellaneous notes and precautions
- (i) References

(2) SOPs Required: The followings are the minimum number of SOPs required:

- (a) Sample receipt and logging
- (b) Chain-of-custody procedures
- (c) Sample storage
- (d) Prevention of sample contamination
- (e) Security for laboratory and samples
- (f) Standard purity and preparation
- (g) Instrument maintenance records and logbooks
- (h) Sample analysis and data control system
- (i) Glassware cleaning
- (j) Internal review of QA/QC data for each data package
- (k) Data reduction and reporting
- (l) Laboratory data validation
 - Data flow and chain-of-command for data review.
 - Procedures for measuring precision and accuracy.
 - Control chart generation and utilization.
 - Evaluation parameters for identifying systematic errors.
 - Internal QA inspection procedures.
 - Documentation of problem identification, corrective actions, and resumption of analytical processing.

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(m) Data management and handling

e. Handling of Confidential Information. A commercial laboratory conducting work under the USACE HTRW contract may receive USACE-designated confidential information. Confidential information must be handled separately from other documentation. To accomplish this, a commercial laboratory should establish the following procedures for the handling of confidential information:

(1) All confidential documents shall be under the supervision of a designated document control officer. In order to provide document accountability of the confidential documents, each item in a specific USACE project file should be inventoried and assigned a serialized number. All documents relevant to each sample delivery group should be inventoried. This includes: logbook pages, bench sheets, mass spectra, chromatograms, screening records, re-preparation records, re-analysis records, records of failed or attempted analysis, custody records, library research results, etc. The designated document control officer shall be responsible for ensuring that all documents generated are placed in the specified project file for inventory.

(2) Any samples or information received with a request of confidentiality shall be handled as "confidential." A separate locked file shall be maintained to store this information and shall be segregated from other nonconfidential information. Data generated from confidential samples shall be treated as confidential. Upon receipt of confidential information, the document control officer will log these documents into a Confidential Inventory Log. The information will then be available to authorized personnel but only after it has been signed out to that person by the document control officer. The documents shall be returned to the locked file at the end of each working day.

(3) Confidential information may not be reproduced except upon approval by the USACE TM/COR. The document control officer shall enter all copies into the document control system described above. In addition, this information may not be disposed of except upon approval by the USACE TM/COR. The document control officer shall remove and retain the cover page of any confidential information disposed of for one year and shall keep a record on the disposition in a Confidential Inventory Log.